



Nomination to ICCVAM: NTP Rodent Bioassay for Carcinogenicity

**Raymond Tice, Ph.D.
Deputy Director, NICEATM**

**June 19, 2008
SACATM Meeting
Research Triangle Park, NC**

Test Method Nomination Time Line (2007)

24 Oct

Nomination received via NTP on-line nomination process that ICCVAM evaluate the validation status of the NTP rodent bioassay to accurately predict human carcinogens and noncarcinogens

Also, as can be seen from the additional publicly available nomination information¹, ICCVAM is being asked to evaluate the suitability of results obtained using this test method as a standard against which the predictive performance of alternative test methods can be objectively measured, and, if the test method cannot be validated, what new data/approaches would be needed to conduct a proper evaluation.

In discussion of the nomination with the nominator, the nominator requested anonymity

¹ <http://iccvam.niehs.nih.gov/SuppDocs/submission.htm>

Test Method Nomination Time Line (2008)

- 23 Jan** ICCVAM considers this nomination in conjunction with currently available information on this test method's usefulness and limitations, and proposes that the evaluation of this test method be assigned a "low priority"
- 23 Apr** ICCVAM reviews "Draft ICCVAM Recommended Priority" document
- 7 May** NTP publishes Federal Register notice announcing SACATM meeting, listing the nomination as an agenda item, and requesting public comment
- 19 Jun** SACATM considers ICCVAM draft evaluation priority for this nomination
- Summer** ICCVAM considers additional nomination materials, public comments, and SACATM comments in setting final evaluation priority

Draft ICCVAM Priority

- *ICCVAM concluded, based on the available information considered and ICCVAM's evaluation priorities¹, an evaluation of the ability of the NTP Rodent Bioassay to accurately identify human carcinogens and noncarcinogens should have a low priority at this time.*
- *However, while this represents the proposed current priority for evaluating the performance of this test method, ICCVAM and NICEATM recognize that future planning and priorities must be flexible in order to take advantage of opportunities resulting from advances in science and technology, development of new test methods, and to respond to new testing needs.*

¹ *the evaluation priorities are described in the NICEATM-ICCVAM Five-year Plan, available at <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>*



Question for SACATM

Do you agree with ICCVAM's draft priority for this nomination? If not, please explain